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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/756,219

01/12/2004

Donald R. Sandell

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MILA KASAN, PATENT DEPT.
APPLIED BIOSYSTEMS
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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/756,219

Applicant(s)

SANDELL, DONALD R.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/20/05 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Pfost et al.(US 5,496,517) or Yamamoto et al.(US 5,102,623) in view of Woudenberg et al.(US 5,928,907).

The reference of Pfost et al. discloses a device capable of thermal cycling that includes a sample block assembly(60); and a sample well tray holder (34) for holding a sample well tray (44). The sample block assembly and sample well tray holder are independently translatable to position a sample well tray in a position for temperature control of the sample well tray (See Figure 6).

The reference of Yamamoto et al. discloses a device capable of thermal cycling that includes a sample block assembly(25,26); and a sample well tray holder (11) for holding a sample well tray (14). The sample block assembly and sample well tray holder are independently translatable to position a sample well tray in a position for temperature control of the sample well tray (See Figure 4).

With respect to claim 36, both of the above references fail to disclose an optical system and/or wherein the sample well tray is positioned to be in alignment with the optical detection system.

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The reference of Woudenberg et al. discloses that it is known in the art to provide a nucleic acid sequencing device with an optical detection system for monitoring the contents of the reaction wells during temperature control of the reaction wells (See Figures 1 and 2).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide either of the temperature control systems of the primary references of Pfost et al. or Yamamoto et al. with an optical detection system in alignment with the reaction chambers during temperature control for the known and expected result of providing real time monitoring of the reaction chambers and related advantages discussed by the reference of Woudenberg et al. (See column 1, line 65, to column 2, line 5). Note the instant claims do not positively recite the sample well tray and/or the samples are part of the claimed device.

With respect to claims 37 and 42, the optical detection system as suggested by Woudenberg et al. would remain stationary since the well plate is being moved relative to the heating location and would be considered a "real-time PCR machine".

With respect to claim 38, both the references of Pfost and Yamamoto et al. disclose the use of a sample block (62 of Pfost and 26 of Yamamoto et al.) for contacting the sample well tray.

With respect to claims 39-41, both the references of Pfost and Yamamoto et al. disclose the use of a positioning mechanism that includes links and motors to translate the sample block (See elements 28-30 of Yamamoto et al. and elements 70, 72 and 74 of Pfost).

With respect to claims 43 and 44, use of the device as suggested by the combination of the references of Pfost et al. or Yamamoto et al. with Woudenberg et al. for nucleic acid

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sequencing reactions, such as PCR, would meet the claim language of claims 43 and 44. If not, in view of the disclosure of Woudenberg et al., the performance of nucleic acid amplification using the modified primary references would have been obvious for the known and expected result of performing an art recognized means for sequencing DNA as is contemplated by all of the references of Pfoest et al., Yamamoto et al. and Woudenberg et al.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 36-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,677,151. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 36-44 are generic to all that is recited in

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claims 1-35 of U.S. Patent No. 6,677,151. That is, claims 1-35 of U.S. Patent No. 6,677,151 fall entirely within the scope of claims 36-44 or, in other words, claims 36-44 are anticipated by claims 1-35 of U.S. Patent No. 6,677,151. Specifically, claims 1-35 of the U.S. Patent No. 6,677,151 encompasses a thermal cycling device and method of use that includes a sample block assembly; an optical detection system; and a sample well tray holder including a tray-receiving region configured to hold a sample well tray, and wherein the sample block assembly and sample well tray holder are independently translatable to position a sample well tray into alignment with the optical detection system.

Terminal Disclaimer

8. The terminal disclaimer filed on 5/20/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,677,151 has been reviewed and is NOT accepted.

a. The person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324.

9. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34

(a). See 37 CFR 1.321(b) and/or (c).

10. It would be acceptable for a person, other than a recognized officer, to sign a terminal disclaimer, provided the record for the application includes a statement that the person is empowered to sign terminal disclaimers and/or act on behalf of the organization.

Accordingly, a new terminal disclaimer which includes the above empowerment statement will be considered to be signed by an appropriate official of the assignee. A separately filed paper referencing the previously filed terminal disclaimer and containing a proper empowerment statement would also be acceptable.

Response to Arguments

11. Applicants' amendments and associated comments filed 5/20/2005 are not persuasive to overcome the 35 USC 103 rejection of record.

Applicant's response merely states that amended independent claims 36 and 43 clarify the present invention. Applicant's comments are silent as to how and/or why the amendments as filed define over the 35 USC 103 rejection of record.

In response, the Examiner maintains that the claims as amended are still met by the combination of the references of Pfoest et al. or Yamamoto et al. with Woudenberg et al. With respect to independent claim 36, the amendment to the claim merely further limits the intended use of the device and not the structure of the device. The Examiner maintains that the device suggested by the combination of the references is structurally capable of operating on a sample well tray that includes nucleic acid amplification samples. With respect to claim 43, if the method encompassed by the combination of the references as discussed does not inherently include nucleic acid amplification, the use of the device as suggested for nucleic acid amplification would clearly be well within the purview of one having ordinary skill in the art since all of the devices are drawn to nucleic acid sequencing procedures and nucleic acid amplification is a well known DNA sequencing process.

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Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269.

The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB